Spring/Summer 2015

# Maryland Board of Pharmacy A Color of Pharmacy A Color of Pharmacy

#### In This Issue

Executive Director's
Message1
State of Emergency
Instructions3
Emergency Preparedness Task Force4
Sale of Needles and Syringes
or Other Paraphenalia4
DEA Number4
2014 Legislative Session5
Biologicals7
Pneumonia Vaccines8
Disciplinary Actions9
Working Conditions Survey
Results10
PDMP11
Overdoses11
Personnel/Contact Information12
Board Commissioners and Board Meeting Dates12

The Mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists; registering pharmacy technicians; issuing permits to pharmacies and distributors; setting pharmacy practice standards through regulations and legislation; receiving and resolving complaints; and educating the public.

Maryland Board of Pharmacy 4201 Patterson Avenue Baltimore, MD 21215 Tel: 410-764-4755 Fax: 410-358-6207





## FROM THE EXECUTIVE DIRECTOR'S DESK LaVerne G. Naesea

Since the last newsletter was published, several events have occurred that will affect the practice of pharmacy, some pharmacies' operations, and activities at the Maryland Board of Pharmacy. One significant event was the Governor's declared State of Emergency in Baltimore City this past April. The civil disturbances in that region of the State caused major losses and damage to over 25 independent and chain store pharmacies. Some pharmacies were damaged to the point of having to temporarily or permanently close. Still other pharmacies opted to change hours of operation or temporarily relocate operations because of perceived threats.

The Board of Pharmacy partnered with affected pharmacy permit holders and Governor Larry Hogan, through the Maryland Emergency Management team (MEMA), and Secretary Van Mitchell of the Department of Health and Mental Hygiene, to address initial safety and security concerns, and assist affected pharmacy patients to fill needed prescriptions in the days immediately following the unrest.

Baltimore City has one of the highest concentrations of Maryland citizens per square mile in the state. Nearly half of the State's low-income minority individuals over age sixty live in Baltimore City. Despite the substantial damage caused, most of the affected pharmacies have expressed a commitment to rebuild and/or continue operating in Baltimore City neighborhoods. The Board commends pharmacy permit holders for their continued commitment to providing medication access to all residents throughout the State. The Board also acknowledges and sends appreciation to Governor Hogan and Secretary Mitchell for their leadership and immediate actions to support affected pharmacy patients and pharmacies during the recent crisis. For more information or to request assistance, please visit the Board's website at: <a href="http://dhmh.maryland.gov/pharmacy/SitePages/State-Of-Emergency.aspx">http://dhmh.maryland.gov/pharmacy/SitePages/State-Of-Emergency.aspx</a>

Also noteworthy this spring was the passage of several legislative bills. Amendment to the *emergency refill* statute provides one clear example

Continued on Page 2

## Executive Director's Desk Continued from Page 1

of how important legislation is to supporting Maryland's pharmacy patients during times of emergencies. Among other changes, the bill increased the quantity of refill medications that could be dispensed during a declared State of Emergency from 14 to 30 days. A second key bill during this year's session repealed the requirements for all sterile compounding practitioners to acquire separate sterile compounding permits from the Board. It is important to note that sterile compounding pharmacies are still required to meet current laws regarding testing and reporting requirements under their existing pharmacy permits. Please review the Legislation and Regulations section of this issue to learn about all of the new pharmacy-related mandates that were passed this year.

The Board celebrated its 113th anniversary in April and began recruiting its very first Deputy of Operations in accordance with its reorganization plan. The recruitment was delayed because a key player in that process, Patricia Gaither, resigned at the end of April. Ms. Gaither, former Manager for the Administration and Public Support Unit, was instrumental in supporting the growth and fiscal stability at the Board since her recruitment in 2004. Her extensive experience and skills in fiscal and personnel management were invaluable. She most recently served, during the recruitment period, in an acting capacity as Deputy of Operations. I speak for the entire Board and Staff in stating that Patricia Gaither's intentions were always honorable and her talents invaluable to the progress made to the Board over the past 12 years.

Unfortunately, Board Commissioners, who play significant roles in the many positive achievements and initiatives of the Board, have terms that also end during this time of year. This year, Lenna Israbian-Jamgochian and Lynette Bradley-Baker will join the list of Board leaders that have left 'footprints' on the Board following eight years of service.

During her tenure, Commissioner Israbian-Jamgochian successfully served on numerous committees, including Disciplinary, Licensing, Practice, and Legislative, as well as on the Sterile Compounding, Sanctions Review, and Inspection Forms Revision sub-committees. She was voted by her Commissioner peers as the Board Treasurer, voting delegate at National Association of Board of Pharmacy (NABP) district and national meetings, and eventually as a two-term Board President, beginning in FY 2014. Lenna always went the extra mile to ensure the Board functioned effectively. Following in her father's footsteps as a second generation pharmacist, she ably balanced her time and responsibilities as a chain pharmacy regional manager with her many leadership roles at the Board. I worked closely with her in efforts to reform and refine dispensing practices in Maryland. Her determination, spirit of consensus, and genial personality led to her success in meeting both the Board's and her personal goals while a member.

Lynette Bradley-Baker also provided solid contributions and leadership during her two terms on the Board. As the Chair of the Emergency Preparedness, and Licensing, Public Relations committees, Commissioner Bradley-Baker freely shared all of her many skills and talents with the Board. She guided development of several new applications to help the Board determine whether pharmacy technician, wholesale distributor, and nonresident and sterile compounding pharmacy applicants met new regulatory requirements. Her editorial review of newsletter content and other official Board documents was invaluable. Lynette shared the value of her knowledge and experiences from a variety of backgrounds, including chain store operations and pharmacy school academia that profoundly enhanced the Board's comprehension of issues presented before it. Lynette brought a certain charm and calm to the Board as she thoughtfully

#### STATE OF EMERGENCY INSTRUCTIONS

If your pharmacy is impacted during an emergency, and is required to temporarily close or relocate, the State of Maryland and Board of Pharmacy are available to provide guidance.

Please notify the Maryland Board of Pharmacy of any damage incurred to your establishment by faxing 410-384-4128 or emailing dhmh. mdbop@maryland.gov and include the following information:

- Name of pharmacy
- Address of pharmacy
- Permit Number
- Type of damage (e.g., looted/vandalized, destroyed)
- Brief summary of operation plans with projected dates (e.g., temporary closure, permanent closure, relocation, etc.)
- Contact phone number

If you are considering relocating permanently or temporarily, certain notifications must also be provided to the Board, including:

- Address for the temporary location
- Floor Plan (schematic only)
- Alarm System information
- A description of any changes to the information included with the pharmacy's original application on file with the Board as business (such hours, emplovee changes, etc.). Please be advised that a new or temporary pharmacy location must be inspected before any business may be conducted. Please direct questions regarding this information to 410-764-4755 between 8:30 am and 5:00 pm Monday through Friday, and the call will be transferred to the correct unit.

#### **EMERGENCY PREPAREDNESS TASK FORCE**

The Maryland Board of Pharmacy (MDBOP) sponsors an Emergency Preparedness Task Force (EPTF) that works closely with the State Office of Preparedness and Response to prepare trained pharmacy personnel who are available during declared States of Emergency. The EPTF has enabled pharmacists to be recognized as being vital members of the State's emergency teams. The MDBOP has been instrumental in writing the State Emergency Preparedness Plan which includes roles for pharmacists, pharmacy technicians and pharmacy establishments.

Currently MDBOP is recruiting new task force members from locations throughout Maryland. If you are interested in serving on the EPTF, as a representative for your specific area of Maryland, please submit your resume and a brief explanation of your interest in becoming an EPTF member to Janet Seeds at <u>janet.seeds@maryland.gov</u> or call 410-764-5988 for more information.

To register as an Emergency Preparedness and Response Volunteer, go to <a href="www.mdresponds.org">www.mdresponds.org</a>. Click onto 'register now.' Registered volunteers may be deployed if pharmacy personnel are required during emergencies.

## NOTICE OF OPPORTUNITY FOR PUBLIC COMMENT REGARDING 10.13.08 SALE OF NEEDLES AND SYRINGES OR OTHER PARAPHERNALIA

In accordance with the Regulatory Review and Evaluation Act, State Government Article, §§10-130—10-139, Annotated Code of Maryland, the Maryland Board of Pharmacy under the Department of Health and Mental Hygiene currently is reviewing and evaluating the above regulations. This review process occurs every 8 years.

You may review the above regulations online at www.dsd.state.md.us.

The Maryland Board of Pharmacy invites interested parties to participate in the review and evaluation process by submitting comments on the regulations by mail to Anna D. Jeffers, Legislation and Regulations Manager, Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215, by fax to (410) 358-6207, or by email to anna.jeffers@maryland.gov.

official notification of this review An and evaluation will also be published Maryland Register. Comments in the received later must be no than August 1, 2015. Parties may contact the Board at (410) 764-4794 with questions about this process.

#### REMINDER: NPI NUMBERS

There is no state or federal requirement for a prescriber to include their DEA number on a prescription for a non-controlled substance. Indeed, some prescribers, for example Optometrists, do not have a DEA number as prescribing controlled dangerous substances is outside of their scope of practice.

As of May 23, 2007, all prescribers/providers in the country are required to have a National Provider Identifier (NPI) number. The NPI is mandated by the Health Insurance Portability and Accessibility Act (HIPAA). All payors are required to honor this new number which will not be related to prescribing controlled dangerous substances. The NPI does not take the place of a payor's credentialing process, but may shorten it.

#### 2015 MARYLAND LEGISLATIVE SESSION RESULTS OF 2015 LEGISLATION TRACKED BY THE MARYLAND BOARD OF PHARMACY

The below chart lists the results of important bills tracked by the Maryland Board of Pharmacy during the 2015 Legislative Session. Cross-filed bills are listed together. For further information on specific legislation see: <a href="http://mgaleg.maryland.gov/webmga">http://mgaleg.maryland.gov/webmga</a> or contact Anna Jeffers, Legislation and Regulations Manager.

Bill #	Bill Name	Result
SB 1	Health Occupations - Pharmacists - Refills of Prescriptions During State of Emergency	PASSED
HB 591	Health Occupations - Pharmacists - Refills of Prescriptions During State of Emergency	PASSED
нв з	Prescription Drug Monitoring Program - Prescribers and Dispensers - Required Query	Unfavorable
SB 14	Health Occupations - Board of Pharmacy - Pharmacist Rehabilitation Committee - Definition	PASSED
HB 748	Health Occupations - Board of Pharmacy - Pharmacist Rehabilitation Committee - Definition	PASSED
HB 58	Health Occupations - Members of Boards and Advisory Committees - Prohibition against Concurrent Service	PASSED
SB 69	State Board of Pharmacy - Sterile Compounding - Compliance by Nonresident Pharmacies and Repeal of Permit Requirement	PASSED
HB 181	State Board of Pharmacy - Sterile Compounding - Compliance by Nonresident Pharmacies and Repeal of Permit Requirement	PASSED
SB 130	Criminal Procedure – Shielding – Misdemeanor Convictions	Unfavorable
SB 526	Maryland Second Chance Act of 2015	Did not cross
HB 244	Maryland Second Chance Act of 2015	PASSED
SB 198	Health Care Disparities, Cultural and Linguistic Competency, and Health Literacy - Continuing Education	PASSED
HB 580	Health Care Disparities, Cultural and Linguistic Competency, and Health Literacy - Continuing Education	PASSED
SB 346	Pharmacists - Scope of Practice - Revisions	Did not cross
HB 657	Pharmacists - Scope of Practice - Revisions	PASSED
SB 347	Health Occupations - Prescriber-Pharmacist Agreements and Therapy Management Contracts	PASSED
HB 716	Health Occupations - Prescriber-Pharmacist Agreements and Therapy Management Contracts	PASSED
SB 516	Public Health - Overdose Response Program	PASSED
HB 745	Public Health - Overdose Response Program	PASSED
SB 537	Pharmacists - Substitution and Dispensing - Interchangeable Biological Products	Did not cross

## 2015 MARYLAND LEGISLATIVE SESSION Continued from Page 5

Pharmacists - Substitution and Dispensing - Interchangeable Biological Products	Did not cross
Public Health - Vaccination Reporting Requirements - ImmuNet	Unfavorable
Registered Nurses - Local Health Departments - Requirements for Personally Preparing and Dispensing Drugs and Devices	PASSED
Registered Nurses - Local Health Departments - Requirements for Personally Preparing and Dispensing Drugs and Devices	PASSED
Dedicated State Funds Protection Act	Unfavorable
Public Health – PDMP – Required Disclosures	PASSED
Public Health – Opioids Time-Lock Dispenser Pilot Program	Did not cross
Health Insurance - Specialty Drugs - Participating Pharmacies	Did not cross
Health Insurance - Specialty Drugs - Participating Pharmacies	Unfavorable
Public Health - Maryland AIDS Drug Assistance Program - Expansion of Eligibility and Services - Pharmaceutical Rebate Coverage	PASSED
Public Health - Maryland AIDS Drug Assistance Program - Expansion of Eligibility and Services - Pharmaceutical Rebate Coverage	Did not cross
Medicaid Managed Care Organizations - Pharmacy Networks - Plan	PASSED
	Biological Products  Public Health - Vaccination Reporting Requirements - ImmuNet  Registered Nurses - Local Health Departments - Requirements for Personally Preparing and Dispensing Drugs and Devices  Registered Nurses - Local Health Departments - Requirements for Personally Preparing and Dispensing Drugs and Devices  Dedicated State Funds Protection Act  Public Health - PDMP - Required Disclosures  Public Health - Opioids Time-Lock Dispenser Pilot Program  Health Insurance - Specialty Drugs - Participating Pharmacies  Health Insurance - Specialty Drugs - Participating Pharmacies  Public Health - Maryland AIDS Drug Assistance Program - Expansion of Eligibility and Services - Pharmaceutical Rebate Coverage  Public Health - Maryland AIDS Drug Assistance Program - Expansion of Eligibility and Services - Pharmaceutical Rebate Coverage

## Executive Director's Desk Continued from Page 2

deliberated on Board decisions and carefully chose her words to relay opinions. Having also served on the Drug Therapy Management and Disciplinary committees, Lynette commanded the respect of her Board peers and was voted to leadership roles on the Executive committee as Board Treasurer and Secretary.

Regardless of the past and future events that the Board will face as it ensures safe dispensing and quality pharmacy services in Maryland, civic role models like Pat Gaither, Lenna Israbian-Jamgochian and Lynette Bradley-Baker help assure the Board's success as its 113 year legacy moves forward. On behalf of the Board, Staff members, and Maryland public citizens, job well done, thank you and God's continued blessings!

The Maryland Board of Pharmacy Commissioners and staff members sadly announce the recent passing of former Board Commissioner Mayer Handelman. During his Board tenure, Mayer Handelman chaired the Disciplinary, Long Term Care and Licensing committees. He worked closely throughout his career with representatives of the long term care pharmacy community, Office of Health Care Quality and others to champion the needs of Long Term Care residents. His successful advocacy efforts to expand and redefine pharmacy care for long term care residents in Maryland will be long remembered.

## BIOLOGICALS, BIOSIMILARS, AND INTERCHANGEABLE BIOLOGIC PRODUCTS

Biological drugs are essential components in the treatment of many disease states. These drugs are always expensive; five of the top ten most prescribed drugs last year were biologics, based on dollars spent. Traditionally, all biologics have been the originator, or brand name, agent. This is about to change.

The Biologics Price Competition and Innovation Act (BPCIA) of 2010 provided for the equivalent of generic products for biological drugs. BPCIA established an abbreviated licensure pathway for such alternative biologicals. This includes the Biologics License Application (BLA), roughly equivalent to the Abbreviated New Drug Application (ANDA) for small molecule drugs. Once approved following the BLA, exclusivity for newly approved biosimilars can be up to one year.

The biologicals differ from traditional drugs, or small molecule drugs, in a number of ways. Biological agents derive from genetically engineered living cells as a routine source and are proteins. They are large, very complex molecules, ranging up to about 150,000 Daltons in molecular size. The structure of biologicals is heterogeneous and highly complex; manufacturing differences can mean major differences in outcomes and risks. There can always be batch to batch variations in the end-result molecule. These drugs are sensitive to heat, light, denaturing, and risk for degradation. Biologic drift can occur, resulting in changes in the base molecule over time. Biologicals are almost always given by injection. The review and approval process for biologic agents is based on the BLA. The "Purple Book" will be a compendium for the biologic agents similar to the generic reference Orange Book.

Alternative products to the originator drug are starting to become available. Newer alternative agents must be considered under two categories – biosimilars and interchangeable biologic products.

A biosimilar is defined as highly similar to the original drug. There are no clinically relevant differences between the biosimilar and the reference product. Interchangeable biologic products are biosimilar to the reference molecule by definition. They have the same clinical effect and outcome as the brand name drug. Interchange from the reference drugs to these alternatives provides the same benefit/risk profile as the reference product. A biosimilar does not necessarily translate to an interchangeable product. The Purple Book will provide separate listings for approved biosimilars and approved interchangeable biologic products.

Examples of biologic drugs include insulin, adalimumab, infliximab, interferon, etanercept, epoetin, filgrastim, and rituximab. The first approved biosimilar is Zarxio®, filgrastim from Sandoz. It has the same indications as Neupogen® but has not been approved for interchange. Four additional biosimilar products are in the pipeline for potential 2015 FDA review.

The Board of Pharmacy continues to monitor developments in this field as well as relevant legislation.

References: FDA website, accessed March 2015; Special Report: Understanding Key Differences Between Biosimilars and Small Molecule Drugs, May 2013.; GABIonline.net, accessed March 2015 <u>www.medscape.com</u> for prescription volume, accessed March 2015

#### PNEUMONIA VACCINES

In response to several inquiries from pharmacists about the differences between pneumonia vaccines currently on the market, Dr. Tim Rocafort, Pharm D., BCACP, Clinical Specialist at the Johns Hopkins Hospital Outpatient Pharmacy and an Assistant Professor of Pharmacy Practice and Science at the University of Maryland School of Pharmacy, provided the following summary to the Board to assist practitioners in determining which vaccine is most appropriate for patients.

Pneumococcal 23-valent Polysaccharide Vaccine (PPSV23) (Pneumovax®23) in the dose and route of 0.5mL intramuscularly which is indicated for the active immunization of:

- Persons ≥ 65 years old
- Persons age 19-64 years old who are:
  - o Cigarette smokers, asthmatics, those patients who have chronic liver disease including cirrhosis and alcoholism
- Persons ≥ 2 years old with chronic illnesses such as
  - o Heart, lung, diabetes;
  - o Functional or anatomical asplenia;
  - o Who have CSF leak, or a cochlear implant;
  - o Who are immunocompromised

Pneumococcal 13-valent Conjugate Vaccine (PCV13) (Prevnar®13) in the dose and route of 0.5 mL intramuscularly which is indicated for the active immunization of children ages 6 weeks to 5 years old.

#### Notes:

- 1. Both the PCV13 and the PPSV23 should be administered routinely in a series to all adults age 65 years and older.
- 2. As of September 2014, the Advisory Committee on Immunization (ACIP) recommends that PCV13 should be administered to adults ages 19 through 64 years who have specific conditions and who have not previously received PCV13. These specific conditions include:
  - a. Immunocompromising conditions (HIV, solid organ transplant, chronic renal congenital failure, or acquired immunodeficiency, nephrotic syndrome, lymphoma, leukemia, generalized malignancy, Hodgkin's disease, multiple functional myeloma), or anatomic asplenia (e.g., sick cell disease)
  - b. Cerebrovascular fluid leak, and
  - c. Cochlear implant.

- 3. PPSV23 is also recommended for ages 2 through 64 with certain conditions, such as:
  - a. Cigarette smokers 19 years and older (these patients should be given PPSV23 ONLY)
  - b. Chronic cardiovascular disease
  - c. Chronic pulmonary disease
  - d. Chronic renal failure
  - e. Alcoholism
  - f. Diabetes mellitus
  - g. Cirrhosis, and
  - h. Solid organ transplantation.

In the event that an adult 65 years and older has received PPSV23 more than 5 years ago, the new 2014 ACIP vaccination guidelines recommend that a patient can now receive either PCV13 or PPSV23 in series with the first PPSV23 vaccination. However, if a patient has no previous pneumococcal vaccine or unknown vaccination history, PCV13 should be given first, followed by a dose of PPSV23 six to twelve months later.

If the patient has one of the conditions listed above, a dose of PCV13 followed by a dose of PPSV23 can both be administered within a 5 year time period; however, they should be administered at least 8 weeks apart. It is important to also note that PCV13 and PPSV23 should not be administered at the same visit.

#### REFERENCES

- 1. Centers for Disease Control and Prevention. Prevention of pneumococcal disease: recommendations for using pneumococcal vaccines among adults 65 years or older. 2014. Web. Accessed February 27, 2015. http://www.cdc.gov/vaccines/ed/ciinc/downloads/2014-10-23/Pilishvili-PneumococcalRecs.pdf
- Centers for Disease Control and Prevention. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2014; 63 (27): 822-825. Web. Accessed February 27, 2015. <a href="http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf">http://www.cdc.gov/mmwr/pdf/wk/mm6337.pdf</a>
- 3. Immunization Action Coalition. Pneumococcal Vaccines (PCV13 & PPSV23). 2014. Web. Accessed February 27, 2015. <a href="http://www.immunize.org/askexperts/experts\_pneumococcal\_vaccines.">http://www.immunize.org/askexperts/experts\_pneumococcal\_vaccines.</a> asp#ppsv23 boosters

DISCIPLINARY ACTIONS						
PHARMACIST	LIC. #	SANCTION	DATE			
Jackie McCall, Jr	21799	Summary Suspension	3/18/15			
Titilayo Akinyoyenu	14917	Summary Suspension	6/23/15			
Jessica McLaughlin	22852	Summary Suspension	6/24/15			
PHARMACY TECHNICIAN	REG. #	SANCTION	DATE			
Melissa Estes	T14926	Probation	7/03/14			
Brandon Moore	T11076	Revoked	1/21/15			
Morgan Paige	T06118	Revoked	1/21/15			
Sheena Collins	T11267	Revoked	2/18/15			
Reginald Sotero	None	Denied	2/18/15			
Destiny Cameron	T13562	Summary Suspension	3/03/15			
LaVerne Hightower	T15546	Summary Suspension	3/16/15			
Amanda Roles	T15126	Summary Suspension	3/15/15			
Louis McMichael	T13180	Revoked	3/18/15			
LeAnn Harmon-Weaver	T01901	Revoked	3/18/15			
Daniel Eacho	Т08870	Revoked	3/18/15			
Roderick Woods	T01837	Suspended	5/18/15			
David Bloch	T09164	Revoked	5/20/15			
Patricia Flowers	T10562	Revoked	5/20/15			
Meagan Jackson	Т07985	Summary Suspension	5/20/15			
Lindy Lewis	T12856	Revoked	6/17/15			
ESTABLISHMENT	PERMIT #	SANCTION	DATE			
Westbury Pharmacy	P05969	Fine	3/12/15			

## WORKING CONDITIONS SURVEY FOLLOW-UP: INITIAL DATA RESPONSE

#### David H. Jones, RPh, FASCP, Board Commissioner

Once again, the Staff and Commissioners of the Maryland Board of Pharmacy (the "Board") extend a sincere thank you to all the pharmacists and pharmacy technicians who responded to the Pharmacist-Pharmacy Technician Working Conditions Survey (the "Survey"). Your time spent on the Survey and your responses are important to the Board.

Board staff members are beginning an analysis of the Survey data received. Information regarding Survey findings and any needed follow up will be forthcoming. A total of 3,475 Surveys were submitted to the Board, of which 2,575 (75%) were completed in their entirety.

Following is a summary of basic data collected:

- 1. Respondents: 63% were pharmacists and 37% were pharmacy technicians.
- 2. Practice settings:
  - a. Hospital/health system 25%
  - b. Independent pharmacy 11%
  - c. Chain pharmacy 53%
  - d. Compounding pharmacy 1%
  - e. Mail order pharmacy 2%
  - f. Not specified 8%
- 3. Hours worked weekly
  - a. Less than 16 9%
  - b. 17 to 31 14%
  - c. 32 to 40 56%
  - d. More than 40 21%
- 4. The top three medication errors noted were
  - a. Wrong directions
  - b. Wrong quantity
  - c. Wrong strength

Several questions on the Survey were not answered by respondents, including questions about:

- 1. Scheduled breaks the highest number of respondents 1,839 (53%) gave No Response (NR);
- 2. Potential medication errors that were made 1,234 NR;
- 3. Mechanical medication errors 1199 NR;
- 4. When medication errors are caught 1175 NR;
- 5. Judgmental errors 1127 NR;
- 6. Documentation of errors 1127 NR;
- 7. Errors caught before the prescription leaves the pharmacy 1123 NR;
- 8. Notification to prescriber 1123 NR;
- 9. Required prescription quota 1192 NR;
- 10. Immunization quota 1186 NR;
- 11. Interruptions/distraction list -1205 NR;
- 12. Medication error causes 1234 NR

The Working Conditions Subcommittee is tasked with review of data and making recommendations for action to the Practice Committee and the full Board. A full set of data has been shared with all Subcommittee members. First discussions have been held with the Board.

Areas identified for additional focus include hours worked, ability to take beaks, and medication errors. The Board will continue to provide updates as it continues its review of pharmacy working conditions that may impact patient safety.

Be alert for the Working Conditions Follow-Up Survey. Coming to you in July! A quick 12 questions to help the Board help you. Please try to respond quickly. Thank You!

## MARYLAND PDMP REGULATIONS AMENDMENT AFFECTING CDS DISPENSERS

Maryland state statute (Health-General §21-2a) requires all pharmacies (with some exceptions) that dispense schedule II-V CDS to report dispensing to the Prescription Drug Monitoring Program (PDMP). Regulations governing the program were recently amended (COMAR 10.47.07, effective June 8, 2015) to include patient telephone number as a mandatory field reported to the PDMP. Starting September 15, 2015, all records reported to the PDMP must include a patient's telephone number, if the patient has one.

What should pharmacists do?

- If a CDS prescription is dispensed, the recipient's telephone number must be included in the pharmacy record.
- If a patient does not have a telephone number, the pharmacist should enter the patient's telephone number as the dispenser's area code followed by zeroes, e.g., 410-000-0000.

- Why were the regulations changed? Prescription records are matched to patient profiles using a probabilistic algorithm that relies on demographic information, including telephone number. Other demographic fields were already mandated for reporting to the PDMP. This regulatory change supports patient record matching for optimal clinical use of PDMP data accessed by Maryland healthcare providers in CRISP (Chesapeake Regional Information System for our Patients, statewide health information exchange).

In July, keep your eyes open for a mailed letter containing more information about this regulatory change from the PDMP!

Questions should be directed to 410-402-8686 or <a href="mailto:dhmh.pdmp@maryland.gov">dhmh.pdmp@maryland.gov</a>

## 2014 ANNUAL REPORT ON DRUG- AND ALCOHOL-RELATED INTOXICATION DEATHS IN MARYLAND

The Maryland Department of Health and Mental Hygiene (DHMH) released the 2014 Drug- and Alcohol-Related Intoxication Deaths in Maryland report on May 19, 2015. The annual report describes trends in the number of unintentional drug- and alcohol-related intoxication deaths, commonly referred to as fatal overdoses, occurring in Maryland during the period 2007-2014. Fighting the heroin and opioid epidemic in Maryland is a major priority of the Hogan Administration. Major findings from the report include:

- A total of 1,039 overdose deaths occurred in Maryland in 2014. This represented a 21 percent increase in the number of deaths in 2014 compared with 2013's data. This also represented a 60 percent increase since 2010.
- Eight hundred eighty-seven or 86 percent of all overdose deaths in 2014 involved opioids

   which include heroin and prescription drugs such as oxycodone, methadone, and fentanyl. Large increases in the number of deaths involving heroin and fentanyl were responsible for the overall increase in opioid-related deaths:
  - o The number of fentanyl-related deaths more than tripled between 2013 and 2014, increasing from 58 in 2013 to 185

- in 2014. The number of fentanyl-related deaths began increasing in late 2013 as a result of overdoses involving an illicit form of fentanyl that increasingly has been mixed with, or substituted for, heroin or other illicit substances.
- o There were 578 heroin-related deaths in 2014, a 25 percent increase over the number in 2013. Heroin-related deaths have more than doubled in Maryland between 2010 and 2014.
- The number of alcohol-related deaths increased by 13 percent between 2013 and 2014, and by 69 percent since 2010.

For more information on this topic, a coalition of stakeholder organizations, led by the National Association of Boards of Pharmacy, recently released a consensus document representing the medical, pharmacist, and supply chain spectrum highlighting the challenges and 'red flag' warning signs related to prescribing and dispensing controlled dangerous substance (CDS) prescriptions.

Another great resource to fight prescription drug abuse is the Prescription Drug Monitoring Program (PDMP). Please visit the PDMP's website for more information and to register.



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### **Maryland Board of Pharmacy**

CONTACT DIRECTORY  Customer Service Center 410-764-4755 - Email: dhmh.mdbop@maryland.gov				
EXECUTIVE				
LaVerne Naesea, Executive Director; Ansha Page, Executive Assistant	General Programs and Operations Issues and Information			
ADMINISTRATION				
Vacant, Administration & Public Support Manager Rhonda Goodman, APS Assistant	Fiscal, Budget, Procurement, Travel, Personnel and Public Information			
LEGISLATION AND REGULATIONS				
Anna Jeffers, Legislation and Regulations Manager Anasha Page, Administrative Assistant	Legislation and Regulations and Pharmacy Practice Issues			
COMPLIANCE				
YuZon Wu, Compliance Manager; Courney Jackson, Compliance Secretary	Practice/Patient Complaints, Disciplinary Actions, Inspections, Compliant Investigations and Pharmacists Rehabilitation			
LICENSING				
LaToya Waddell, Licensing Manager; Vacant, Licensing Secretary	Licensing, Permits, Registrations Reciprocity, Certifications, Scores and Verifications			
MANAGEMENT INFORMATION SERVICES				
John Johnson, MIS Manager	Database statistics and Rosters, Website Host and On-line Renewals			
Toll Free 1-800-542-4964				

#### **BOARD COMMISSIONERS**President: **Mitra Gavgani**

Secretary: David Jones
Treasurer: Jermaine Smith

Daniel Ashby Lynette Bradley-Baker Lenna Israbian-Jamgochian Roderick Peters Trinita Robinson Charmaine Rochester Sajal Roy Zeno W. St. Cyr, II Bruce Zagnit Home Infusion Representative Long Term Care Representative Chain Representative

Acute Care Representative
At-Large Representative
Chain Representative
Independent Representative
Consumer Representative
At-Large Representative
Acute Care Representative
Consumer Representative
Independent Representative

#### **BOARD MEETINGS**

Public Pharmacy Board meetings begin at 9:30 a.m. on the third Wednesday of each month and are open to the public. The Board encourages all interested parties to attend the monthly Board Meetings.

#### 2015 PUBLIC BOARD MEETINGS DATES

#### Third Wednesday of each month

August 19, 2015

September 16, 2015 (NOTE: September meeting will be at the Frederick Memorial Hospital) October 31, 2015

Location: 4201 Patterson Avenue, Baltimore, MD 21215